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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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1444	7590	11/04/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			ROSENZWEIG, JASON	
624 NINTH STREET, NW				
SUITE 300			ART UNIT	
WASHINGTON, DC 20001-5303			PAPER NUMBER	
			3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/800,004	Applicant(s) JUDY, WILLIAM V.	
	Examiner Jason E. Rosenzweig	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07192004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 07/19/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Crossed out references were either not translated or illegible by the examiner and therefore they have not been considered.

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

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2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities: The abbreviation "DFT" is not adequately disclosed, upon search in prior art the abbreviation "DFT" could be defined as the following:

- 1- Diastolic Filling Time
- 2- Discrete Fourier Transform.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 8, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Regarding claim 1, the statement "Device for determining at least a left ventricular and diastolic volume LVEDV for a heartbeat..." Is indefinite in that it does not have any upper bounds and claims determining a volume for any segment and any time point within the heart. It is suggested to remove the term "'at least'" after "Device for determining". Furthermore the statement "...a processing unit, connected to said measuring means, for processing and outputting at least a value of said impedance signal..." is also rejected to since the claim encompasses outputting any type of measured value from a measuring means. Again it is suggested to remove the term "'at least'" after "...for processing and outputting".

7. Regarding claim 8, the term "Method for determining at least a left ventricular end diastolic volume LVEDV..." is indefinite as it does not have any upper bounds and claims a method for determining any measurement for any segment and any time point within the heart. It is suggested to remove the term "'at least'" after "Method for determining".

8. Regarding claim 15, the term "said impedance signal z_0 substantially equals the average value of at least 5, and preferably at least 10 preceding values of said impedance signal z_0 " is indefinite as it is unclear as to whether the value should be at least 5 or that there should be at least 5 samples, also the word "'preferably'" is not needed.

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9. Claim 6 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

10. Regarding claim 6, the term "a manner known per se" is indefinite and could result in different manners of determining stroke volume. It is suggested to remove the term "'as determined in a manner known per se,'" after "...instantaneous stroke volume of said heart,"

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi (US 6370424) in view of the teachings of Granerus.

14. Regarding claim 1, Prutchi discloses: Device for determining at least a left ventricular end diastolic volume LVEDV (Col. 7, Ln. 51) for a heartbeat of a beating heart of mammal, in particular a human being, having a body having a thorax, the device comprising a current source for producing an alternating current with a frequency (Fig 2)

- One or more upper supply electrodes and one or more lower supply electrodes (Fig 3), which can be applied to said body of said mammal and which can be connected to said current source, for supplying said alternating current to said body,
- One or more upper measuring electrodes and one or more lower measuring electrodes, which can be applied to said body of said mammal above said heart, below said heart, respectively, for receiving an impedance signal that depends on the impedance of a part of said thorax (Fig 3, Element 110) at least comprising said heart,
- Measuring means, connected to the measuring electrodes (Fig 3, Element 119), measuring said impedance signal which is received by the measuring electrodes (Fig 3, Element 118; see abstract),

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- A processing unit (Fig 3, Element 117), connected to said measuring means, for processing and outputting at least a value of said impedance signal and a first time derivative of said impedance signal (Col 3, Ln 8), wherein the device further comprises means for determining a duration DFT of a diastolic filling time (Col 7, Ln 39) of said heart during said heartbeat and for determining a value of said impedance signal at the end of a pre-ejection period (Col 7, Ln 41) of said heart during said heartbeat, which diastolic filling time and pre-ejection period may be determined in manner known per se, and wherein said processing unit is inherently capable of outputting said value of said left ventricular end diastolic volume LVEDV.

Prutchi does not disclose of determining and outputting said value of said left ventricular end diastolic volume LVEDV in dependence of both said duration DFT and said value of said impedance signal and the difference of said value of said first time derivative of said impedance signal between the beginning and the end of said pre-ejection period.

Granerus teaches stroke volume measurement by impedance cardiography using a formula based on the delta z waveform, specifically determining value of left ventricular end diastolic volume LVEDV in dependence of both said duration DFT and said value of said impedance signal and the difference of said value of said first time derivative (Fig. 1) of said impedance signal between the beginning and the end of said pre-ejection period. It would be obvious to one of ordinary skill in the art to combine the disclosure of Prutchi and the teachings of Granerus to utilize a more

accurate non-invasive method of using impedance values to calculate cardiac output using changes in impedance across the thorax due to changes in blood volume.

Regarding Claim 2, 3, 9, and 10, Prutchi substantially discloses the device of claim 1 except for he does not specify the use of a phonocardiogram or a means for determining said duration, Diastolic Filling Time or DFT, comprising of an electronic circuit, which is able to determine said duration DFT as the time between the moment at which said first time derivative assumes a third local minimum value following a maximum value during said heartbeat, and the moment at which said first time derivative assumes a local minimum value immediately before the next maximum value.

Granerus specifically discloses a circuit for recording a impedance cardiograph along with the use of a phonocardiogram (Pg. 133, First Paragraph), along with a method of calculating said duration DFT as the time between the moment at which said first time derivative assumes a third local minimum value (Figure 1) following a maximum value during said heartbeat (Figure 1), and the moment at which said first time derivative assumes a local minimum value immediately before the next maximum value, using simultaneous recording of both ECG and Phonocardiogram (PCG) data. It would be obvious to one of ordinary skill in the art to modify Prutchi in view of Granerus to have a device, which can calculate a DFT duration using both ECG and PCG data.

Regarding Claims 4, 5, and 12, Prutchi substantially discloses the device of claim 1 however he does not specifically disclose a formula in which said processing unit outputs said left ventricular end diastolic volume LVEDV as

$$LVEDV = C \cdot \left(\frac{L}{M_0} \right)^2 \cdot DFT \cdot \Delta \frac{dZ_M}{dt}$$

Granerus specifically discloses a method of calculating stroke volume (SV) (Pg. 133, Below Figure 1), which is substantially similar to calculating LVEDV; the equations are substantially similar except for variable labels used. It would be obvious for one of ordinary skill in the art to take the device of Prutchi and modify it such that it would contain a processing unit which could non-invasively output left ventricular end diastolic volume using the specified formula above even though Prutchi's disclosure is capable of already producing enough information to derive a measure of LVEDV (Col 7, Ln. 36).

Regarding claims 6 and 14, Prutchi substantially discloses: A device according to claim 1, but does not disclose of a processing unit which could further output the ejection fraction (EF) as $EF = SV / LVEDV$; The examiner takes official notice that this formula is common knowledge to someone of ordinary skill in the art, further the formula is disclosed in the acor.org reference. It would therefore be obvious to one of ordinary skill in the art to use the above formula for ejection fraction in a processing unit to output a value for ejection fraction from both LVEDV and Stroke Volume.

15. Regarding claim 7, Prudchi substantially discloses the device of claim 1 but does not further specify the use of both strip and spot electrodes.

16. Granerus specifies the use of both strip electrodes (Pg. 132, Section 2.2) and inherently the use of spot electrodes for the third and fourth electrodes. It would be obvious based upon the teachings of Granerus to modify Prudchi to utilize both strip and spot electrodes around the neck since they are better suited for use in the area around the neck.

17. Regarding claim 8, Prudchi substantially discloses: A method substantially similar to the device claim 1 and further includes determining left ventricular end diastolic volume LVEDV as described in the claims above.

18. Granerus does not disclose of a specific value Z_0 which is the value of said impedance signal at the end of a pre-ejection period with a specific value equal to 0.54 ± 0.02 . It would have been obvious to one having ordinary skill in the art at the time the invention was made to experimentally determine the variation of a impedance signal at the end of a pre-ejection period in order to improve the accuracy a cardiac output calculation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

19. Regarding claim 11, Prutchi in view of Granerus substantially discloses the device of claim 8, wherein said one or more upper measuring electrodes are applied to the mid neck region (Pg. 132, Section 2.2) and said one or more lower measuring

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electrodes are applied at the height of the xiphoid junction of said sternum (Pg. 133, First Paragraph).

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Granerus as applied to claims 1-12, and 14 above, and further in view of Jaakko (Bioelectromagnetism).

21. Regarding claim 13, Prutchi in view of Granerus substantially discloses the device of claim 12 however neither specifically specify a formula which could be used to determine the resistivity of blood of a mammal, but they do mention the fact that blood volume does affect the measured impedance across the thorax. In further view of the teachings of Jaakko who discloses the formula for calculating resistivity of blood (Equation 7.11) it would be obvious to modify Prutchi in view of Granerus and in further view of Jaakko to implement a method to calculate the resistivity of mammalian blood based upon the Fricke Equation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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